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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,314	01/26/2001	Graham D. Marshall	32020-8001US1	7648

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EXAMINER	
GORDON, BRIAN R	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/771,314	MARSHALL ET AL.
	Examiner	Art Unit
	Brian R. Gordon	1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1-8-04*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43-47* is/are rejected.

7)☒ Claim(s) *48* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *1-8-04* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to canceled claims 1-42 have been considered but are moot in view of the cancellation of claims 1-42. A new ground of rejection is given herein.

Applicant asserts that the novelty of the invention is that of how the central processing unit lists, groups, and performs tasks. Task managers are conventional and well known in the art. For example, Windows Operating Systems comprise electronic tasks managers that display tasks requested by the operator and commonly ordered and grouped in the order of the requests. As such the examiner asserts that the task manager as claimed is not novel with respect to conventional computer and control systems.

Claim Interpretations

2. Claim 47 is directed reservoir containing a lyophilized or a concentrated reagent. The claim requires a reservoir that contains one or the other of the above substances. Furthermore, a concentrated reagent may be any reagent presence. The term "concentrated" the claim is a relative term. The term "concentrated" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Therefore any reagent may be considered concentrated to some degree.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 43-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uffenheimer US 5,558,838.

Uffenheimer discloses a sample preparation apparatus which includes a pair of valves. A first valve selectively communicates a sample tube with a vent/aspiration

valve, or alternatively communicates a diluent pump with a reaction tube. By moving the first valve, one may selectively relieve a vacuum within a sample tube, aspirate a sample from the tube, or alternatively may drive a diluent and a sample into the reaction tube. The second valve is a vent/aspiration valve which selectively communicates the first valve to two distinct systems. A first system vents a vacuum in the sample tube, and a second system aspirates a sample from the sample tube. The second valve is actuated to initially relieve any vacuum in the sample tube, and is then actuated to connect the aspiration system to the sample tube to begin to withdraw of a sample from the sample tube. At the same time, the diluent pump is filled. The shear valve is then moved to communicate the diluent pump to the reaction tube. The diluent pump is actuated to drive a diluent and a sample slug into the reaction tube, which preferably contains a predispensed reagent. This system simplifies the valving structure over the prior art systems. In addition, a unique rinse system provides a rinse solution to the outer periphery of the needle, while the needle is connected to a source of suction to withdraw the rinse fluid. Finally, a unique structure for holding and properly positioning the reaction tube provides a control signal indicating that a reaction tube is received in the reaction tube structure. If no reaction tube is sensed, a **controller** deactivates the system such that no fluids are dispensed by the system.

A sample preparation apparatus 20 is illustrated in FIG. 1 including a control panel 22 for controlling the operation of the system. A tube guide 24 (cartridge support with alignment member) receives a closed sample tube 26 (reagent cartridge with a reservoir) including closure 28 (penetrable septa). Tube guide 24 guides sample tube

26 downwardly onto a **needle** 30 which punctures the closure 28. As will be explained below, any vacuum in the tube will be vented at that time. The sample may then be aspirated from the sample tube 26 and delivered to a reaction tube 32. A diluent pump 34 (fluid propulsion) communicates to the reaction tube 32 through a shear valve 36. Preferably, reaction tube 32 contains a predispensed reagent.

As shown in FIG. 2A, **needle** 30 has punctured the closure 28 and line 41 communicates with the interior of sample tube 26 (reagent cartridge) through needle 30. As shown in FIGS. 2A, and 2B, a rinse line 42 communicates with a chamber 44 at the outer periphery of the needle 30. Rinse line 42 is connected to a rinse fluid 46 through a pump 48. As will be explained below, after a sample is aspirated from sample tube 26, needle 30 is retracted and rinse fluid is delivered to chamber 44 to clean needle 30.

As also shown, a sample loop or passage 50 extends through shear valve 36. In addition, a groove 52 connects a diluent fluid 54 through a line 56 to a line 58 leading to diluent pump 34.

As shown in FIG. 2A, shear valve 36 (a stream selection device) is in a position where passage 50 communicates line 41 (tubing) from needle 30 to a passage 60. Passage 60 will be termed a "valve passage" for purposes of this application as it connects the two main valves of this invention. Passage 60 passes through conductivity **detector** 61, and communicates with a vent/aspiration valve 62 having a passage 64. In the position shown in FIG. 2A, passage 64 communicates passage 60 to a passage 66 leading to a check valve 68 which is in turn connected to atmosphere at 70. A conduit or line 72 is selectively communicated with passage 64 to communicate a pump 74 and

waste reservoir 76 to line 60. In a second position of shear valve 36, a passage 59 is communicated through shear valve 36 to the diluent pump 34 to send a sample and diluent to the reaction tube 32, as will be explained below.

Applicant asserts that the device of Uffenheimer does not disclose automated operation.

The examiner asserts that applicant's device requires some degree of manual operation to program the device or to activate or initiate the operation of the device. The control panel bottons (A, O, and P) are simply the aspirate, override and power functions.

Uffenheimer does not specifically disclose that the device is automated.

However, the aspirate button is pressed to begin the aspirate processing, but there after depressing the button the device performs all other operations automatically.

Furthermore, It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device by adding an automation means since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. *In re Venner*, 120 USPQ 192.

7. Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Uffenheimer US 5,558,838 as applied to claims 43-46 above, and further in view of Tremmel et al. US 5,171,538 or in the alternative Mack et al. US 6,149,872.

Uffenheimer does not disclose that the reagent cartridge contains a lyophilized reagent.

Tremmel discloses a reagent supply system for a medical anlytical instrument includes a reagent space provided on the instrument and reagent vessels which are received in the reagent space. In the reagent space there is provided at least one reagent vessel compartment with a bottom, lateral guide elements, and a top guiding element, as well as a front stop. The instrument contains a fluid communication system for connection with a reagent vessel situated in the reagent vessel compartment. On the end face of the reagent vessel compartment is disposed a hollow needle near the bottom surface thereof and extending in a direction which is parallel to the bottom surface. The reagent vessel has on its front wall facing the end face a pierceable seal with a pierceable elastic stopper.

Mack et al. dislcose a modular reagent cartridge (10) which includes a plurality of reagent containers (12 to 18) directly interconnected by integrally formed coupling devices (22). The connection is brought about by form-locking rail guides. The invention relates to a reagent cartridge for the supply of ready-to-use, biochemical reagents in liquid form, whose purpose is to enable a simple loading into and use in a fully automatic analyzer.

It would have been obvious to one of ordinary skill in the art at the time of the invention to recognize that a cartridge may also be used to supply a reagent to the system of Uffenheimer.

8. Claims 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laska et al. US 5,104,808.

Laska et al. disclose an apparatus for effecting a plurality of assays on a plurality of samples in an automatic analytical device. The apparatus is adapted to receive a plurality of reaction vessels, and having a plurality of sequentially located processing positions, means to stepwise index the reaction vessels in sequence to the several processing positions for an analysis cycle, the index means effecting at least two such analysis cycles, the positions having means to add sample and/or reagents, to incubate, to wash, or to measure the contents of the vessels..

The processing means are controlled according to different time-templates, each time-template controlling a different set of immunoassays to effect the first use of the wash means in the same cycle. The processing means time-template permit multiple assays to be performed simultaneously using different groups of reaction vessels.

A central processing unit (CPU) housed in the apparatus and now shown is used to read in operating system software and to store system parameter changes and test results. A sample and reagent wheel 22 is used to support sample cups and special reagents. Vessels used to store reagents common to all assays are shown as 24, 26 and 32. Reaction vessels are grouped in clusters.

Laska et al. does not specifically disclose a task manager as claimed by applicant.

However, task managers are conventional and well known in the art. For example, Windows Operating Systems comprise electronic tasks managers that display tasks requested by the operator and commonly ordered and grouped in the order of the

requests. As such the examiner asserts that the task manager as claimed is not novel with respect to conventional computer and control systems.

It would have been obvious to one of ordinary skill in the art at the time of the invention to recognize that the device Laska et al. may be modified to incorporate the conventional task managers to view order and status of the applications or processes requested to be performed by the device.

Allowable Subject Matter

9. Claim 48 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The prior art does not teach nor fairly suggest a device that comprise a reagent reservoir that includes a porous frit, to facilitate mixing of the solvent with the lyophilized or concentrated reagent, and to prevent residual solids from being drawn from the reagent reservoir with the reconstituted reagent.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Safir et al. and Lee-Alvarez disclose liquid transfer systems.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

brg

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